K012992

OCT - 3 2001

510(k) SUMMARY

MASIMO®
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Submitted by:	Masimo Corporation 2852 Kelvin Ave Irvine, CA 92614-5826 (714) 250-9688 FAX (714) 250-9686
Company Contact:	James J. Cronin, Vice President, Regulatory Affairs/Quality Assurance
Date Summary Prepared:	September 5, 2001
Trade Names	LNOP-Ear Sensor, LNOP-YI Sensor, NR7 Sensor
Common Names	Pulse Oximetery Sensors SpO2 Ear Sensor
Classification Names	Oximeter (74DQA) (870.2700) Cable, Transducer and Electrode (74DSA) (870.2900) Oximeter, Ear (74DPZ) (870.2710)
Substantially Equivalent Devices	Masimo SET Radical Pulse Oximeter with SatShare™ and LNOP series of Sensors and Cables 510(k) Number - K000126 Nellcor DURA-Y Oxygen Transducer, Ear Clip - 510(k) Number - K944760

Description

The Masimo series of oximetry sensors measure the light absorption of blood from two light emitting diodes (LED's). Oxygen saturated blood absorbs light differently than unsaturated blood. The amount of light absorbed by the blood is used to calculate the ratio of oxygenated hemoglobin to total hemoglobin in arterial blood. This filing includes the addition of 2 reusable sensors and a disposable sensor.

Intended use

The additional Masimo series of sensors are intended for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor) for adult, pediatric, and neonatal patients in hospitals, hospital-type facilities, mobile, and home environments.

Indications For Use:

The additional Masimo series of sensors are indicated for the following:

Single use oximetry sensor intended for adults and pediatrics greater than 10 kg
Reusable oximetry ear sensor intended for adults and pediatrics greater than 30 kg
Reusable oximetry multisite sensor intended for adults, pediatrics, and neonates greater than 1 kg

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Comparison to Predicate Devices:

The additional Masimo series of sensors all use the same theory and principle of operation as the predicate devices.

Performance Data and Conclusions:

Performance testing was conducted on adult volunteers. The additional series of sensors were compared to arterial blood samples analyzed on a laboratory CO-Oximeter. Accuracy (Arms) for the NR7 was ± 2%, for the LNOP-Ear ± 3.5%, and for the LNOP-YI for adults and pediatrics ± 2% and ± 3% for neonates over the range of 70% to 100% SaO_2.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 3 2001

Mr. James J. Cronin
Masimo Corporation
2852 Kelvin Avenue
Irvine, CA 92614-5826

Re: K012992
Masimo SET® Radical Pulse Oximeter with SatShare™ and the Masimo Series of Sensors (LNOP-Ear Sensor, LNOP-YI Sensor, NR7 Sensor)
Regulation Number: 870.2700, 870.2710
Regulation Name: Oximeter, Ear Oximeter
Regulatory Class: II (two)
Product Code: 74 DQA, 74 DPZ
Dated: September 5, 2001
Received: September 6, 2001

Dear Mr. Cronin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K012992

Device Name: Masimo SET® Radical Pulse Oximeter with SatShare™ and the Masimo Series of Sensors and Cables

Indications For Use:

The following additional Masimo Sensors are indicated for the continuous noninvasive functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate:

Single use oximetry sensor intended for adults and pediatrics greater than 10 kg
Reusable oximetry ear sensor intended for adults and pediatrics greater than 30 kg
Reusable oximetry multisite sensor intended for adults, pediatrics, and neonates greater than 1 kg

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012992

Prescription Use ✓ **or** **Over-The-Counter Use** _____
(Per 21 CFR 801.109)

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(Optional Format 1-2-96)